K051063

Polyaxial Hemispherical Spinal Screws

510(k) Summary

April 21, 2005

MAY 2 3 2005

Submitter

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Contact person

J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Trade Name Polyaxial Hemispherical Spinal Screws

Common name Posterior pedicle screw system

Classification name Class II per 21 CFR section 888.3070

Product Code MNI/MNH

Equivalent Device Scient'x ISOBAR Hemispherical Screw system (K990118).

Device Description

The ISOBAR Spinal System consists of monoaxial and polyaxial pedicle screws rods, nuts and cross link members. (K990118, K013447 and K031290) It can be used for single or multiple level fixation. It also includes single and double hooks (K013444 and K013440) used for posterior, nonpedicle screw fixation of the noncervical spine, hook and sacral/iliac screw fixation to the noncervical spine and hook and sacral screw fixation to the T1-S1 spine.

The modification included in this submission is the addition of polyaxial hemispherical screws. These screws function in the same manner as the previously cleared hemispherical screws by insertion into the pedicle then placing an offset clamp over the screw with a rod that has been loaded into the clamp. A nut is them placed on the screw and tightened to secure the assembly. The new polyaxial screw allows the proximal portion of the screw to angulate in order to ease the assembly of the rod loaded clamps onto multiple screws that may not be axially aligned.

Intended Use

The Polyaxial Hemispherical Spinal Screws are intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease(DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

As a pedicle screw system the Polyaxial Hemispherical Spinal Screws are intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Summary Nonclinical Tests

Testing was performed per ATM F1717 and the results are comparable to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2005

Scient'X
C/o Mr. J.D. Webb
The Orthomedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K051063
Trade/Device Name: Polyaxial Hemispherical Spinal Screw
Regulation Number: 21 CFR 888.3070, 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNI, MNH, KWP
Dated: April 21, 2005
Received: April 26, 2005

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam Provost

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Polyaxial Hemispherical Spinal Screws

Indications for Use:

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"Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown."

"**Precaution:** The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient."

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K051063